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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,779	04/20/2001	Amin I. Kassis	U0381-00001	2010

8933 7590 10/06/2003

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EXAMINER
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WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/839,779

Applicant(s)

KASSIS ET AL.

Examiner

Jon P Weber, Ph.D.

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

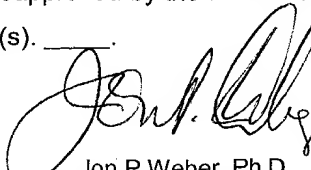
Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit: 1651

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It is argued that neither Hansen (US 5,851,527) nor Griffiths et al. (US 6,361,774) teach that the agent once cleaved from the conjugate forms a water insoluble precipitate or that it is trapped in the extracellular space.

The quoted portion of Hansen in the response as noted in the Office action of 08 July 2003 clearly states that the free drug is deposited on the cell membrane surrounding the cells. The free drug is the one released from the (more water soluble) conjugate. Deposition is a synonym for precipitation. As noted prior Office action, the interstitial region surrounding the cells is the extracellular space. Accordingly, Hansen clearly meets the limitations of the claims. A similar argument has already been made at page of the Office action of 03 February 2003 with respect to Griffiths, citing column and line number supporting that the prodrug is cleaved to an insoluble form that deposits at the enzyme cleavage site.

The rejections under 103 are traversed on the basis that the secondary references do not remedy the same alleged deficiency in Hansen (US 5,851,527) and Griffiths et al. (US 6,361,774).

None of the relied upon references are needed to remedy said alleged deficiency because the primary references are not so deficient. The reasons for relying on these references are set forth in the Office actions of 03 Feb 2003 and 08 Jul 2003.

Applicant's arguments filed 09 September 2003 have been fully considered but they are not persuasive. The rejections under 35 U.S.C. 102 and 103 are adhered to for the reasons of record and the additional reasons above.

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